

## REMARKS

In an Office Action mailed December 28, 2001, the Examiner in charge of the above-noted application imposed a requirement for restriction and, conditionally, a requirement for species election in the above-noted case.

### Restriction

The bases for requiring restriction are set forth on pages 2-5 of the Office Action and are not repeated herein. As a complete reply to the Office Action requires provision election by the applicants, applicants provisionally elect Group I, traversed as above, and respectfully requests that at least Claims 10-19 and preferably all claims, be reclassified in Group I and examined with the elected group for the reasons described below. Applicants traverse both aspects of the requirement for restriction for the reasons described below. In addition, certain claims are amended for clarity and consistency.

The pending claims include three broadly stated claims for controlling body fat, inhibiting lipoprotein lipase activity associated with a cell, and reducing triacylglyceride level in a cell, where each effect is accomplished by reducing lipoxxygenase activity. These three processes are set forth in independent Claims 1, 20, and 34 respectively.

The Examiner asserts that inventions I-II and III-IV and V-VI are unrelated. MPEP Section 806.04 (Independent Inventions) requires that the claims be both (1) not disclosed as capable of use together and (2) having different modes of operation, different functions or difference effects. The three groups of inventions are, in fact, disclosed as related. Paragraph [0027] describes that the aforementioned methods for controlling total body fat percentage can be assessed (1) by measuring a reduction in lipoprotein lipase enzyme activity or (2) by measuring a reduction in triacylglycerides in fat cells. These related processes are in striking contrast to the exemplary independent inventions of MPEP Section 806.04, namely a process of painting a house and a process of boring a well. Here, a clear relation exists among the effects of the methods as well as the steps for carrying out the methods.

The Examiner further indicated that, within each group, inventions I and II, III and IV, V and VI are unrelated. While it is true that CLA is known to reduce body fat in an animal, there is no indication that CLA reduces body fat by reducing lipoxxygenase activity.

Therefore, it is improper of the Examiner to assert in Group II that control of body fat in this method as amended is achieved by administration of CLA.

A dependency error in the claims is noted and an amendment is presented to cure this error. Claim 10 should properly depend from Claim 2 rather than Claim 1. Support for this

amendment appears in the specification, for example, at page 27, paragraph [0026]. This amendment affects the restrictions of Groups I and II. Claims 10-14 should form a part of Group I as administering CLA is a further step in addition to administering a lipoxxygenase inhibitor. Further, although Claim I recites reducing lipoxxygenase activity to control body fat, there is no indication that CLA itself reduces lipoxxygenase activity although CLA is known to reduce body fat by other physiological processes. Accordingly, the entire reference to CLA in Claims 1 and Claims 15-19 in Group II is without basis. All of Claims 1-19 relate to controlling body fat by generically reducing lipoxxygenase activity (Claim 1); more specifically either by administering a lipoxxygenase inhibitor in the absence or presence of CLA (Claims 2-14) or by lowering lipoxxygenase level (Claims 15-16). Claims 17-19 simply enumerate certain animals in which body fat can be controlled by reducing lipoxxygenase activity. As all of the approaches of Claims 2-16 are described in the application as ways to reduce lipoxxygenase activity, the claims are capable of use together and therefore are not independent inventions.

The same is true of Groups III and IV, wherein the inhibition of LPL activity, described in the specification as being related to control of body fat, can be accomplished by generically reducing lipoxxygenase activity, more specifically either by inhibiting lipoxxygenase or by lowering lipoxxygenase level. Again, a skilled artisan would appreciate the relationship of these complementary and related methods.

Finally, the same applies for the related method for reducing triacylglyceride level by generically reducing lipoxxygenase activity (Claim 34). As before, lipoxxygenase activity can be reduced either by treating with a lipoxxygenase inhibitor in the absence or presence of *trans*-10, *cis*-12 CLA, or by lowering lipoxxygenase level, optionally by treating the cell with an antisense oligonucleotide of lipoxxygenase mRNA.

It is further noted that the Examiner has included Claims 31 and 45 in groups IV and VI, each drawn to a method of using an antisense oligonucleotide to inhibit heparin-releasable lipoprotein lipase or to reduce triacylglyceride levels, respectively. Claims 31 and 45 should not be part of these groups, as the claims make no reference to such an oligonucleotide; rather the claims more broadly recite reducing lipoxxygenase activity in the methods by lowering lipoxxygenase level. Only dependent Claims 32 and 46 specify using an antisense oligonucleotide in this context.

### Species Election

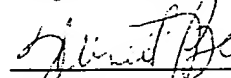
As Group I is provisionally elected, applicants are required to elect a species, namely a single disclosed lipoxxygenase inhibitor. Applicants elect nordihydroguaiaretic acid (NDGA), with traverse. The requirement is traversed because the lipoxxygenase inhibitors disclosed in the application have already been characterized as such and the use of any such inhibitor in the method involves no new or surprising interaction between lipoxxygenase and an inhibitor thereof. Rather, the invention relates to recognizing a novel effect of inhibiting lipoxxygenase, no matter the method for doing so. The ability to include a set of compounds related by function and used interchangeably in the method imposes no undue burden, even though those compounds may be classified separately. Applicants here claim only methods which can readily be searched. Should the Examiner wish to search the art associated with the compounds, this is readily accomplished using standard searching tools.

Further, the applicants are required to elect a single disclosed species of animal acted upon by the method. For purposes of examination, applicants elect the mouse, but traverse the requirement in view of the understanding in the art that the activity of lipoxxygenase in oxidation of arachidonic acid to produce eicosanoid metabolites is known to be conserved in animals, as noted in the specification at paragraph [0006] and as taught in paragraph [0018]. The mouse is a rodent as recited in Claim 18, although all of Claims 1-18 are relevant to the elected animal.

No fee is believed due in connection with this response, but should any fee be due in this or any subsequent response, please charge the fee to Deposit Account No. 17-0055. Likewise, no extension of time is believed due, however, should an extension of time be due in this or any subsequent response, please consider this to be a request for an appropriate extension of time and a request to charge the fee due to the same deposit account.

Reconsideration of the requirements for restriction and election, and consideration of the merits of this application are respectfully requested.

Respectfully submitted,



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Examiner: Karl J. Stiller

For: ANIMAL BODY FAT CONTROL

Docket: 960296.97958



1. (Amended) A method for controlling body fat in an animal, the method comprising the step of:  
reducing lipxygenase activity in the animal by an amount sufficient to control body fat in the animal.
2. (Amended) A method for controlling body fat in an animal, the method comprising the step of:  
administering a lipxygenase inhibitor to the animal [at a dose] in an amount sufficient to control body fat in the animal.
6. (Amended) The method of claim 5, wherein the NDGA [dose ranges] is fed in an amount from about 0.01% to about 5% by weight in diet.
7. (Amended) The method of claim 5, wherein the NDGA [dose ranges] is fed in an amount from about 0.05% to about 1% by weight in diet.
8. (Amended) The method of claim 5, wherein the NDGA [dose ranges] is fed in an amount from about 0.1% to about 0.5% by weight in diet.
10. (Amended) The method of claim [1] 2, further comprising the step of:  
administering [CLA] an agent that comprises trans-10, cis-12 conjugated linoleic acid (CLA) to the animal.
11. (Amended) The method of claim 10, wherein [administering is feeding] the

agent is fed to the animal.

12. (Amended) The method of claim 11, wherein the [dose of CLA ranges] agent comprises *trans*-10, *cis*-12 CLA in an amount from about 0.01% to about 5% by weight in diet.

13. (Amended) The method of claim 11, wherein the [dose of CLA ranges] agent comprises *trans*-10, *cis*-12 CLA in an amount from about 0.05% to about 1% by weight in diet.

14. (Amended) The method of claim 11, wherein the [dose of CLA ranges] agent comprises *trans*-10, *cis*-12 CLA in an amount from about 0.1% to about 0.5% by weight in diet.

16. (Amended) The method of claim 15, wherein the lowering step includes the step of administering [into] to the animal an oligonucleotide that reduces or prevents translation of a lipoxxygenase enzyme.

20. (Amended) A method for inhibiting LPL activity associated with a cell comprising the step of:  
reducing lipoxxygenase activity in the cell by an amount sufficient to inhibit LPL activity associated with the cell.

21. (Amended) A method for inhibiting LPL activity associated with a cell comprising the step of:  
treating the cell with [a] an amount of a lipoxxygenase inhibitor [at a dose] sufficient to inhibit LPL activity associated with the cell.

23. (Amended) The method of claim 22, wherein the cell is treated with lipoxxygenase inhibitor [concentration is from] at a concentration from about 0.1  $\mu$ M to about 5 mM.

24. (Amended) The method of claim 22, wherein the cell is treated with lipoxygenase inhibitor [concentration is from] at a concentration from about 10  $\mu$ M to about 500  $\mu$ M.

25. (Amended) The method of claim 22, wherein the cell is treated with lipoxygenase inhibitor [concentration is from] at a concentration from about 30  $\mu$ M to about 200  $\mu$ M.

26. (Amended) The method of claim 21, wherein the lipoxygenase inhibitor [is] comprises an anti-lipoxygenase antibody.

27. (Amended) The method of claim 21, further comprising the step of:  
treating the cell with [CLA] an agent that comprises *trans*-10, *cis*-12  
conjugated linoleic acid (CLA).

28. (Amended) The method of claim 27, wherein the agent comprises *trans*-10, *cis*-12 CLA at a concentration [ranges] from about 0.1  $\mu$ M to about 5 mM.

29. (Amended) The method of claim 27, wherein the agent comprises *trans*-10, *cis*-12 CLA at a concentration [ranges] from about 10  $\mu$ M to about 500  $\mu$ M.

30. (Amended) The method of claim 27, wherein the agent comprises *trans*-10, *cis*-12 CLA at a concentration [ranges] from about 30  $\mu$ M to about 200  $\mu$ M.

31. (Amended) The method of claim 20, wherein the reducing [lipoxygenase activity is accomplished by] step comprises the step of lowering lipoxygenase level in the cell.

32. (Amended) The method of claim 31, wherein the lowering [lipoxygenase level is accomplished by] step comprises the step of treating the cell with an antisense oligonucleotide of lipoxygenase mRNA.

34. (Amended) A method for reducing triacylglyceride level in a cell comprising the step of:

reducing lipoxygenase activity in the cell by an amount sufficient to reduce triacylglyceride level in the cell.

35. (Amended) A method for reducing triacylglyceride level in a cell comprising the step of:

treating the cell with a lipoxygenase inhibitor [at a dose] in an amount sufficient to reduce the triacylglyceride level in the cell.

37. (Amended) The method of claim 35, wherein the cell is treated with lipoxygenase inhibitor [concentration is from] at a concentration from about 0.1  $\mu$ M to about 5 mM.

38. (Amended) The method of claim 35, wherein the cell is treated with lipoxygenase inhibitor [concentration is from] at a concentration from about 10  $\mu$ M to about 500  $\mu$ M.

39. (Amended) The method of claim 35, wherein the cell is treated with lipoxygenase inhibitor [concentration is from] at a concentration from about 30  $\mu$ M to about 200  $\mu$ M.

40. (Amended) The method of claim 35, wherein the lipoxygenase inhibitor [is] comprises an anti-lipoxygenase antibody.

41. (Amended) The method of claim 35, further comprising the step of:  
treating the cell with [CLA] an agent that comprises *trans*-10, *cis*-12 conjugated linoleic acid (CLA).

42. (Amended) The method of claim 41, wherein the agent comprises *trans*-10, *cis*-12 CLA at a concentration [ranges] from about 0.1  $\mu$ M to about 5 mM.

43. (Amended) The method of claim 41, wherein the agent comprises *trans*-10, *cis*-12 CLA at a concentration [ranges] from about 10  $\mu$ M to about 500  $\mu$ M.

44. (Amended) The method of claim 41, wherein the agent comprises *trans*-10, *cis*-12 CLA at a concentration [ranges] from about 30  $\mu$ M to about 200  $\mu$ M.

45. (Amended) The method of claim 34, wherein the reducing [lipoxygenase activity is accomplished by] step comprises the step of lowering lipoxygenase level in the cell.

46. (Amended) The method of claim 45, wherein the lowering [lipoxygenase level is accomplished by] step comprises the step of treating the cell with an antisense oligonucleotide of lipoxygenase mRNA.

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